K072356

510(k) SUMMARY

JUN 24 2008

510(k) Owner:	Alfa Wassermann Diagnostic Technology, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Dennis Taschek Phone: 973-852-0177 Fax: 973-852-0237
Date Summary Prepared:	June 19, 2008
Device:	Trade Name: S-Test CA Reagent cartridge Common/Classification Name: Calcium Test System (21 C.F.R. § 862.1145) Product Code CJY Classification: Class II
Predicate Devices:	Manufacturers for analyzer/reagent system predicates are: 1. ACE plus ISE/Clinical Chemistry System ACE Calcium Reagent (K931786) 2. Ortho Clinical Diagnostics Fusion Clinical Chemistry Analyzer Calcium Reagent (K946090) 3. Piccolo® xpress Chemistry Analyzer Calcium Reagent (K942782)
Device Description:	The S-Test Calcium (CA) reagent cartridge, used with the S40 Clinical Analyzer, is intended for quantitative *in vitro* diagnostic determination of CA in serum or heparin plasma based on a photometric test measuring the formation of a reddish-purple complex under strong alkaline conditions.
Intended Use:	The S-Test Calcium Reagent is intended for the quantitative determination of calcium concentration in serum or heparin plasma using the S40 Clinical Analyzer. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany (intermittent muscular contractions or spasms). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Technological Characteristics:	The S-Test CA Reagent is contained in a bi-reagent cartridge. Reagent 1 contains monoethanolamine buffer and 8-hydroxyquinoline. Reagent 2 contains *o*-cresolphthalein complexone.
Performance Data:	Performance data on the S-Test CA included precision, accuracy, and sensitivity data. Precision: In testing conducted at three CA levels for 21 days, the within-run CV ranged from 1.1 to 1.2%, and total CV ranged from 1.6 to 2.2%. In precision studies at three separate Physician Office Laboratory (POL) sites and in-house over five days, the within-run CV ranged from 0.4 to 3.9% and total CV ranged from 0.7 to 4.3%. Accuracy: In the correlation study, 181 samples with CA values ranging from 2.4 to 14.5 mg/dL were assayed on the S40 Clinical Analyzer using S-Test CA and a comparison method. Least-squares regression analysis yielded a correlation coefficient of 0.978, a standard error estimate of 0.4, a confidence interval slope of 0.950 to 1.003, and a confidence interval intercept of -0.30 to 0.17. In patient correlation studies at four separate POL sites using the S40 Clinical Analyzer and a comparison method, least-squares regression analysis yielded a correlation coefficients in the range of 0.929 to 0.965, standard error estimates of 0.49 to 0.68, confidence interval slopes of 0.833 to 1.048, and confidence interval intercepts of -0.62 to 1.54. Sensitivity: The detection limit was 2.3 mg/dL.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 4 2008

Alfa Wassermann Diagnostic Technologies, Inc.
c/o Mr. Daivd Slavin
Vice President, Quality and Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

Re: k072356
Trade/Device Name: S Test Calcium Reagent cartridge
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Code: CJY
Dated: June 16, 2008
Received: June 17, 2008

Dear Mr. Slavin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Alfa Wassermann Diagnostic Technology, Inc.
510(k) Submission K072356

S40 Clinical Analyzer
S-Test CA

Indications for Use Statement

510(k) Number (if known): K072356

Device Name: S-Test Calcium (CA)

Indications for Use: The S-Test Calcium Reagent is intended for the quantitative determination of calcium concentration in serum or heparin plasma using the S40 Clinical Analyzer. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany (intermittent muscular contractions or spasms). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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